

Notice of Allowability

Application No.

10/648,371

Examiner

Sharmila S. Gollamudi

Applicant(s)

BOROWY-BOROWSKI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/28/05 7/18/05
2. ☐ The allowed claim(s) is/are 1-18 and 21-23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Wayne Anderson on September 28, 2005.

The application has been amended as follows:

Please cancel claims 19-20 and 24-27.

Claim 4. A composition according to claim 3, wherein the oil is selected from the group ~~consists~~ consisting of flaxseed oil and fish oil.

Claim 11. A method according to claim 10, ~~wherein step e)~~ the concentration step is effected by evaporation under reduced pressure.

Claim 12. A water-soluble composition comprising a solubilizing agent selected from the group consisting of polyoxyethanyl- α -tocopheryl sebacate (PTS) and polyoxyethanyl tocotrienyl sebacate (PtrienS), and a compound selected from the group consisting of a tocotrienol, formulated in a ratio of solubilizing agent to tocotrienol of about 5.5:1 w/w and coenzyme Q₁₀, formulated in a ratio of solubilizing agent to coenzyme Q₁₀, of 2.5:1 to 3.5:1 w/w.

Claim 13. A water-soluble composition according to claim 12 comprising a solubilizing agent selected from the group consisting of polyoxyethanyl- α -tocopheryl sebacate (PTS) and polyoxyethanyl tocotrienyl sebacate (PtrienS), and a tocotrienol, formulated in a ratio of solubilizing agent to tocotrienol of about 5.5:1 w/w.

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Claim 21. A water-soluble composition comprising polyoxyethanyl- α -tocopheryl sebacate (PTS) and α -tocopheryl acetate formulated in a ratio of 2:1 to 5.5:1 w/w.

Claim 22. A composition according to claim 21, comprising PTS-400 ~~PCS-400~~ and α -tocopheryl acetate, formulated in a ratio of PTS-400 ~~PCS-400~~ to α -tocopheryl acetate of 2:1 to 4.5:1 w/w.

Claim 23. A composition according to claim 21, comprising PTS-600 ~~PCS-600~~ and α -tocopheryl acetate, formulated in a ratio of PTS-600 ~~PCS-600~~ to α -tocopheryl acetate of 5.5:1 w/w.

Reasons for Allowance

Claims 10-11 are rejoined and the restriction requirement for claims 10-11 is rescinded and subsequently allowed. However, the restriction of claims 19-20 and 27 on 6/3/05 is maintained. Applicant agreed to cancel claims 19-20 and 27.

The following is an examiner's statement of reasons for allowance:

Firstly, applicant has overcome the potential obviousness double patenting rejection by filing a Terminal Disclaimer over US 6,045,826.

The closest prior art WO 91/17626 teaches coupling ubiquinone to a solubilizing moiety such as polyoxyethanyl-cholesteryl sebacate to form a water-soluble ubiquinone compound. However, firstly WO '626 differs from the instantly claimed invention since the instantly claimed water-solubilizing agents (polyoxyethanyl- α -tocopheryl sebacate, polyoxyethanyl-sitosterol sebacate, and polyoxyethanyl-cholesteryl sebacate respectively) are not reacted with the lipophilic agent to form *one* compound. Rather the instant claims are directed to a

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composition comprising the two components, i.e. the water solubilizing agent and the bioactive lipophilic agent. Secondly, there is no motivation to utilize another active agent such as instantly claimed polyunsaturated fatty acids, terpenes, terpenoid, or tocotrienol respectively since WO '626 is solely directed to ubiquinones.

Independent claim 12 is directed to a water-solubilizing agent selected from either polyoxyethanyl- α -tocopheryl sebacate, polyoxyethanyl-sitosterol sebacate and an active agent selected from coenzyme Q10 or tocotrienol. Although WO '626 teaches an intermediate reactant solution containing polyoxyethanyl-cholesteryl sebacate and ubiquinone, there is no motivation, (other than hindsight motivation) in WO '626 or the prior art to replace the cholesteryl with the instant tocotrienyl or tocopheryl claimed.

US 6846489 is also cited since it mentions polyoxyethanyl-cholesteryl sebacate. However, it is noted that '489 firstly teaches away from its use and secondly teaches polyoxyethanyl-cholesteryl sebacate use in forming a liposome. The instant claims are drawn to a water-soluble composition and thus there is not motivation to look to this reference since polyoxyethanyl-cholesteryl sebacate is used in forming a liposome . US 5908861 also teaches polyoxyethanyl-cholesteryl sebacate but also teaches it in a laundry list of components that may be used to form a liposome.

Therefore, it is the examiner's position that the prior art does not fairly teach or suggest the instantly claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

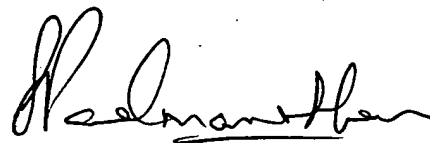
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
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SSG



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